

Notice of Allowability

Application No.

09/886,311

Applicant(s)

KNUDSEN ET AL.

Examiner

Art Unit

Abdel A. Mohamed

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment and remarks filed 12/22/06 and telephonic interview of 1/19/07.
2. ☒ The allowed claim(s) is/are 92,96-99,104-106,122 and 123.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/312,177.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070119</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard W. Bork on 1/19/07.

This application has been amended as follows:

Amendment to the specification:

Replace the paragraph at page 31, lines 5-10 with the followings:

US 5424286 describes a method for stimulating insulin release with exendin polypeptide(s). The Exendin polypeptides disclosed include HEGTFTSDLSKQMEEEEAVRLFIEWLKNGGX (SEQ ID NO:1); wherein X = P or Y, and HX1X2GTFITSDLSKQMEEEEAVRLFIEWLKNGGPSSGAPPPS (SEQ ID NO:2); wherein X1X2 = SD (exendin-3) or GE (exendin-4). Accordingly to this document the insulintropic effect of these polypeptides is greater than that attainable by administration of GLP-1.

Replace the paragraphs at page 35, lines 17-26 with the followings:

In another preferred embodiment, the parent peptide is HEGTFTSDLSKQMEEEEAVRLFIEWLKNGGX (SEQ ID NO:1), wherein X = P or Y, or a fragment or an analogue thereof.

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In another preferred embodiment, the parent peptide is
HX1X2GTFITSDLSKQMEEEAVRLFIEWLKNGGPSSGAPPPS (SEQ ID NO:2), wherein
X1X2 = SD or GE, or a fragment or an analogue thereof.

In another preferred embodiment, the parent peptide is
DLSKQMEEEAVRLFIEWLKNGGPSSGAPPPS (SEQ ID NO:3), or a fragment or an
analogue thereof.

Amendment to the claim:

In the claim:

Replace the claim as follows:

Claim 92 (Currently amended) A derivative of exendin-4 or a fragment thereof, wherein
said derivative has one lipophilic substituent attached, optionally via a spacer, to an
amino acid residue of said exendin-4 or fragment thereof, which is not the N-terminal or
C-terminal amino acid residue of said exendin-4 or fragment thereof, wherein said
fragment has insulinotropic activity.

CONCLUSION AND FUTURE CORRESPONDANCE

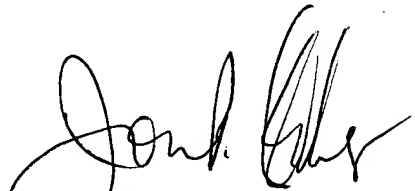
Claims 92, 96-99, 104-106, 122 and 123 are allowed.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Abdel A. Mohamed whose telephone number is (571)
272 0955. The examiner can normally be reached on First Friday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON WEBER
SUPERVISORY PATENT EXAMINER

 Mohamed/AAM
January 19, 2007